

years. Who drove him "nuts"? Can Mr. McClaughry assure us the regulatory state will provoke no more such incidents? If not, shouldn't we analyze the cause?

Michelle Dumas of Somersworth, N.H.—an officer of the New Hampshire Libertarian Party—responded to these charges in a letter to the *Foster's Daily Democrat* last October, writing: "Any reader of Vin Suprynowicz's book clearly understands that the book does not—in absolutely any way—glorify the violent tragedy perpetrated by Carl Drega. As Mr. Suprynowicz clearly states himself, the book could easily have been titled 'The Ballad of Donald Scott,' in reference to the California businessman shot dead in his own home by agents raiding his ranch on a bogus drug allegation.... But the true message of the book ... is about looking behind these needless deaths at the root causes, so that we may find a way to prevent them in the future...."

Perhaps an author should feel complimented when his work comes to merit its own, dedicated gadfly. Among others who hastily condemned my book—unread—were former New Hampshire Governor Jeanne Shaheen and Vermont Libertarian Party Chairman Brendan Kinney.

The most succinct reply, I believe, came when Jim Davies of New Hampshire answered Mr. Kinney:

"Hi, neighbor....

"When the Drega incident occurred, I wrote on it in my then-weekly newspaper column across the Connecticut River with a view very close to your own; though even then, I drew some fire for being too nearly sympathetic to what one reader called a simple murderer.

"Having read Vin's account of the story early in his book *The Ballad*, I've changed my mind. I think he has it about right. Obviously, as Libertarians we can't go around urging people to follow his example, and very likely, Drega was not a man who had systematically thought out his position as academically as we like to.

"But as I see it, he did not initiate force. He was patient with force initiators for years and years, but then eventually snapped.

"Might he have done better to kill aggressors other than those he did kill? Possibly. But that's the risk they run; they taunt and taunt and strut their thing and fling their tin-pot authority around, and then eventually someone in total, nothing-to-lose desperation strikes back...."

Vin Suprynowicz
Las Vegas, NV

Response to Critics on the Adverse Effects of Thimerosal in Childhood Vaccines

[Editor's Note: Some vociferous criticisms have been made of the article concerning possible adverse effects of thimerosal published in our spring issue. To date, however, no one has been willing to send a signed letter for publication. Because the critique has been widely circulated by internet, as in reference 18 below, we offered the authors an opportunity to respond.]

The United States is in the midst of a devastating epidemic of neurodevelopment disorders. Statistics from the U.S. Department of Education on autism in children aged 6 to 21 years served by the Individuals with Disabilities Education Act (IDEA) showed an increase from 11,956 cases in 1992-1993 to 97,329 in 2001-2002, an increase of 714 percent.¹ (Data for each state are found in Table 1 appended to the internet posting of this letter at www.jpands.org.) Between 9 and 15 percent of all children aged 6 to 17 years were served under IDEA during the 1999-2000 school year.

In light of the threat of this epidemic to the very existence of our society, it is not surprising that our recent article,² in which we have shown an epidemiologic link between thimerosal and neurodevelopment disorders, has generated tremendous controversy. We would like to respond to some of the erroneous statements made about our work.

Some object to our use of the Vaccine Adverse Event Reporting System (VAERS) database to conduct an epidemiologic assessment. No database is perfect. Inherent limitations include incomplete reporting, misreporting, and under-reporting. We employ various methods to control for these limitations.

As an example, we have evaluated rotavirus vaccine and intussusception, a recognized complication of rotavirus immunization.³ We determined that, prior to the introduction of rotavirus vaccine, not one case of intussusception had been reported following more than 50 million doses of Diphtheria-Tetanus-whole-cell-Pertussis (DTwP) vaccines. We then evaluated cases of intussusception reported in 1999 following DTwP and rotavirus vaccines, which were both administered at 2, 4, and 6 months of age in the U.S. We found that only 4 percent of cases of intussusception were misreported as being associated with DTwP vaccines, rather than with concurrently administered rotavirus vaccine.

Additionally, we evaluated cerebellar ataxia reported following DTwP vaccine in comparison to Diphtheria-Tetanus-acellular-Pertussis (DTaP) vaccine.⁴ A previous report from Japan had shown that

cerebellar ataxia was reported with similar frequency following these vaccines. It was hypothesized that popular media reports of the risk of serious neurologic disorders following DTwP vaccine might cause overreporting to VAERS. However, our results showed virtually the same frequency of reports of cerebellar ataxia following DTwP and DTaP vaccines (0.29 per million vaccinations vs 0.30 per million vaccinations, respectively), essentially the same rate as was expected based upon the Japanese data, confirming the validity of VAERS reports.

Governmental agencies have previously conceded that the VAERS database may be used for "hypothesis proving." By using a vaccine control group and the Biological Surveillance Summaries of the CDC, we and others have been able to undertake a statistical epidemiologic assessment of the VAERS, as was previously developed and published by Rosenthal et al.⁵ from the National Immunization Program (NIP) of the CDC. Specifically, they reported that, "Rates of reported adverse events per 100,000 vaccinations were significantly lower [P < 0.001] after administration of diphtheria and tetanus toxoids and acellular pertussis vaccine than diphtheria and tetanus toxoids and pertussis vaccine for the following outcomes: all reports, 2.2 vs 9.8; fever, 1.9 vs 7.5; seizures, 0.5 vs 1.7; and hospitalizations, 0.2 vs 0.9." In addition, Sever et al.⁶ from the Anthrax Vaccine Expert Committee (AVEC), have examined the VAERS database, "...to assess the causal relationship between vaccination and reported adverse events.... Six events qualified as serious adverse events, and all were judged to be certain consequences of vaccination."

The VAERS database provides a perspective regarding adverse events following vaccination that is available by no other means of analysis. More than 200,000 adverse event reports are recorded in the VAERS database following more than one billion doses of more than 30 different types of vaccines administered as part of the U.S. National Immunization Program. No data set will ever be able to provide this much information about the actual clinical effects of such a large number of immunizations of so many different types.

Most epidemiologic studies encounter this problem: "Several social and medical attributes are associated both with avoidance or delay of vaccination.... Studies that fail to control adequately for such confounding factors are likely to underestimate the risks of adverse events attributable to vaccination."⁷ Analyses of the VAERS database using the CDC's methods of comparing one vaccine to another, instead of comparing vaccine recipients to a background population, circumvents this difficulty because equal avoidance or delay

of vaccination is likely for both vaccine populations under study.

Our calculation of the instantaneous exposure of U.S. infants to thimerosal from childhood vaccines in comparison to the Federal Safety Guidelines has also been criticized, citing the 2001 Institute of Medicine (IOM) report,⁸ which found that the dose to infants from vaccine was only slightly in excess of the Guidelines. The IOM calculated exposure in the first six months (180 days) of life by dividing the dose received in the vaccines by 180. By this method, the infants were barely in excess of the Environmental Protection Agency (EPA) limit of 0.1 mcg of methylmercury/kg/day, but not in excess of the Food and Drug Administration (FDA) limit of 0.4 mcg/kg/day. (Since that report was published, the FDA has lowered its maximal permissible oral dose of methylmercury to concur with the EPA limit.)

Applying the IOM method to a newborn weighing 3 kg, hepatitis B vaccine containing 12.5 mcg of mercury gives a dose 39 times the daily permissible oral intake, and this cannot be hidden by dividing by the child's age (1 day).

We believe the IOM method of calculation to be absolutely erroneous and extremely misleading. By this method, if a 55-year-old man were given a lethal dose of ethylmercury today, the dose averaged over the number of days in his lifetime would not exceed EPA or FDA limits, but he would still be dead.

The FDA and EPA maximal permissible doses for the oral doses of methylmercury are daily instantaneous maximal doses, and the vaccines administered to children are instantaneous exposures to mercury. Thus, the appropriate calculation finds that infants were, when thimerosal was present in childhood vaccines, exposed to instantaneous levels of mercury that were many-fold (i.e. in some cases more than 100-fold) in excess of the Federal Safety Guidelines for the oral ingestion of methylmercury.

Some have objected to our applying the Federal Safety Guidelines for the oral ingestion of methylmercury to exposures from injected ethylmercury from thimerosal. The IOM itself uses this comparison. Moreover, injection results in much greater absorption of mercury than does oral ingestion.

Criticism of our estimates of mercury dosage appears to be based on a misunderstanding of the information available from VAERS. The VAERS database states which dose was associated with the adverse event; thus, we were able to determine the approximate amount of mercury that the child had been exposed to from previous immunizations. Because VAERS records the vaccine manufacturer, we could, by reviewing the Physician's Desk Reference (PDR) and the 2001 IOM Report, determine how much thimerosal was present in

each vaccine under study. Unfortunately, we were unable to provide the identities of the vaccine manufacturers or the number of doses distributed based upon the Biological Surveillance Summaries of the CDC, which are broken down by manufacturer. The CDC claims that this information is proprietary and required us to agree not to divulge it, as a condition of being given access to these summaries.

Some argue that the CDC's summaries do not accurately reflect the dosages administered to children, but others rely on that data. As Rosenthal et al.⁹ state: "The annual numbers of pertussis-containing vaccine doses administered during the period from 1991 to 1993 were estimated from the Centers for Disease Control Biologics Surveillance. This surveillance system receives voluntary reports from all manufacturers of doses distributed and doses returned by providers, thereby permitting calculation of net doses distributed, an approximation of doses administered."

We have also been attacked for our analysis of the data from the Vaccine Safety Datalink (VSD) database because neither the original preliminary VSD study of thimerosal and neurodevelopment disorders nor any of the follow-up expanded studies identified a "signal" indicating any association between thimerosal and autism. This statement is incorrect regarding the VSD and neurodevelopment disorders.

A complete review of the relevant VSD studies was published in the 2001 IOM report.⁸ In a study of 114,966 children in HMO-B, increasing ethylmercury dosage was associated with a statistically significantly increased adjusted risk of any neurodevelopment disorder, stammering, language delay, and speech delay. In a study that analyzed 15,309 children in HMO-A for only a limited number of types of neurodevelopment disorders, increasing dosage of ethylmercury was associated with a statistically significantly increased adjusted risk of stammering and emotional disturbances.

The IOM then considered information from the Phase II study that was conducted by the CDC group using the Phase I study design in an East Coast HMO (i.e. Harvard Pilgrim of Massachusetts). In this study it was only possible to analyze attention deficit disorder and speech delays. Based upon an examination of 17,500 children, there were no significant differences in risk of these two outcomes associated with receipt of thimerosal-containing vaccines.

In the light of these inconsistent results, the IOM found that the studies were inconclusive with regard to causality. However, further examination shows that IOM was seriously misled by this presentation. A review of the U.S. Department of Education data concerning autism in children 6 to 21 years old shows that the overall prevalence of autism increased by

435 percent from 1992-1993 to 1999-2000. This report shows that California, where the VSD Phase I studies were conducted, had a 422 percent increase in autism during this period, while Massachusetts, where the Phase II study was conducted, had only a 10 percent increase in autism over the same period. A general review of the U.S. Department of Education data shows that every state in the United States, with the exception of Massachusetts, experienced a greater than 100 percent increase in autism, and many states experienced a many thousand percent increase in autism during this period. Thus, the CDC's method was able to show an effect where an effect was present, and returned a negative result in the state with the least increase in autism. Thus, we believe that these CDC studies strongly support a causal relationship between the increasing mercury from thimerosal-containing childhood vaccines and the increase in neurodevelopment disorders.

Our attempts to gain access to the VSD database began before the CDC's press release announcing that the VSD was opened to the public at the end of August 2002. Despite more than 10 months of communication, and our providing the CDC with a cashier's check for about \$3,200 out of our own pockets, we still have not been given access to the VSD database. Moreover, we have been told that outside investigators will have no access to data regarding thimerosal and neurodevelopment disorders until the CDC publishes an analysis of this material — much of which has been in its possession since 1999.

The 2001 U.S. Department of Education Report provides a completely independent source and method that strongly confirms previous epidemiologic assessments.

Some have cast aspersions on the editors and peer reviewers of the *Journal of American Physicians and Surgeons* for publishing our article. This is also a direct assault on major peer-reviewed journals that have previously published articles by us that used similar methods. Additional articles by us are in press.^{9,10} Many other authors using a variety of study methods will soon publish papers that confirm and extend our work, such as a study by Baskin et al.¹¹ demonstrating that thimerosal in micromolar concentrations rapidly induces membrane and DNA damage, and initiates caspase-3 dependent apoptosis in human neurons and fibroblasts, and a study by Holmes et al.¹² on significantly different mercury levels in the first baby haircuts of autistic children in comparison to normal controls. The association of thimerosal in vaccines and other medical products with neurodevelopment and other disorders is very real and simply cannot be denied.

We have been criticized for failing to comment on a recent article by Nelson and Bauman,¹³ which appeared after our article

was written. These authors do not acknowledge several recent epidemiologic studies that have shown an increase in the prevalence of autism from about 1 in 2,500 children in the mid-1980s to about 1 in 150 children by 2002.¹⁴⁻¹⁷ Their arbitrary statement that ethylmercury is not like methylmercury in its effects is without basis, is contrary to published data, and even ignores the conclusion of the 2001 IOM Report regarding the biological plausibility of the relationship between ethylmercury from thimerosal in childhood vaccines and neurodevelopment disorders. Finally, their article is simply a commentary and was published before our epidemiologic data that support the hypothesized relationship.

We are stunned by this assertion in an official statement by the American Academy of Pediatrics (AAP)¹⁸ concerning our article: "The authors claim falsely that children in the United States in 2003 may be exposed to higher levels of mercury from thimerosal contained in childhood immunizations than any time in the past, when in fact, all routinely recommended infant vaccines currently sold in the United States are free of thimerosal as preservative and have been for more than 2 years." Regrettably, our comments are true and can be verified by anyone. A simple review of the 2003 PDR indicates that thimerosal is present at 25 mcg per dose (i.e. in full strength) in multidose vials of DTaP vaccine manufactured by Aventis Pasteur, haemophilus influenza Type b (Hib) vaccine manufactured by Wyeth, Td vaccine (recommended for children > 7 years old) manufactured by Aventis Pasteur, and all influenza vaccines (influenza vaccine is now recommended for most children). Additionally, the PDR indicates that Merck makes a pediatric hepatitis B vaccine that contains 12.5 mcg per dose and adult hepatitis B vaccine that contains 25 mcg of mercury per dose. The package inserts of these vaccines also indicate that they still contain the original amounts of thimerosal. In addition, a sequential review of previous PDRs indicates that in 2002 and 2001 there were even more vaccines listed as containing thimerosal. Are we to assume that these products are mislabeled and actually do not contain thimerosal as the AAP insists?

A recent article authored by Kelly Patricia O'Meara in *Insight on the News* has apparently answered our question, by an interview with Len Lavenda, a spokesman for Aventis Pasteur, who stated regarding the PDR and package insert for DTaP vaccine manufactured by Aventis Pasteur: "In March 2001 we stopped all sales of that product in the preservative formulation...The PDR is outdated...The current package insert does not accurately reflect what is being marketed."¹⁹ We feel that the admitted mislabeling of vaccine is a situation that cannot be tolerated in medicine.

There has been much discussion about how we fund our studies. We have never received one penny from anyone to conduct any studies but have funded all of our research out of our own limited resources. Dr. Geier has been paid as an expert witness and as a consultant in hearings before the Vaccine Compensation Act and in civil litigation involving adverse reactions. Similarly, David Geier has been a consultant in hearings before the Vaccine Compensation Act and in civil litigation involving adverse reactions to vaccines. However, as of the acceptance of our three papers on thimerosal and neurodevelopment disorders, we had never received any money from any cases alleging damage from thimerosal.

Assertions that we are anti-vaccine is belied by a review of our publications. We have opposed the current position of the World Health Organization (WHO) that poliomyelitis vaccination can be stopped within the foreseeable future.²⁰ We have also argued for a need to reintroduce a newly formulated vaccine to combat the alarming 30-fold increased incidence of Lyme disease in the United States from 1982 to 1996.²¹

As Fine and Chen have stated, "No intervention is entirely without risk..."²² We as physicians and scientists have an obligation to conduct open and frank discussions about the safety and efficacy of vaccines. We believe that there is no doubt that continued immunizations are critical to our safety and welfare, but we need a concerted effort to improve the safety and efficacy of existing vaccines. Those who apparently have been injured by a vaccination should report their adverse reaction to the VAERS database and are entitled to rapid, non-litigious, and generous justice before the National Vaccine Injury Compensation Program (VICP).

Personal assaults on us and on the journals in which we publish, along with denying the existence of the tragic massive autism epidemic, will neither cure the problem, nor will it restore confidence in our much needed vaccine program. Rather, we must admit our past mistakes openly and honestly, and then work to improve current and future vaccines. The first step in this process is the immediate removal of thimerosal from all vaccines, which we predict will result in the end of the autism epidemic.

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